

July 19, 2022

PR-ORD-22-01447/SOL 68HERC22R0228
Proposal No. 10005942

Dahnish Shams
Contracting Officer
ORD/CPHEA/CPAD
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 8602R, Room No. 71205
Washington, DC 20460

Dear Mr. Shams:

In response to Solicitation No. PR-ORD-22-01447/SOL 68HERC22R0228, we are pleased to submit the enclosed proposal, prepared by our Board on Environmental Studies and Toxicology (BEST), requesting support for Technical Expertise Support on Environmental Protection Agency (EPA) Scientific Issues and Topics 2022. The total estimated cost is \$48,336 for the period of September 1, 2022 to August 31, 2023.

The National Academies of Sciences, Engineering, and Medicine will assist EPA by identifying experts for an EPA-led workshop to obtain information and views on scientific questions pertaining to the assessment of human health effects from exposure to cobalt.

Acceptance of funds for this activity is subject to approval by the Executive Committee of the National Research Council Governing Board at its meeting on August 4, 2022.

Mr. Raymond Wassel is the responsible staff officer for this activity. He may be contacted regarding program matters at (202) 334-2617. Business negotiations are the responsibility of Mr. Russell Walker, Contract Manager, Office of Contracts and Grants. He may be reached at 202-334-2004.

We shall appreciate your consideration of this matter.

Sincerely,



Elizabeth Eide, Ph.D.
Executive Director

Enclosures

**Awards resulting from this proposal should be issued to
NATIONAL ACADEMY OF SCIENCES**

DIVISION ON EARTH AND LIFE STUDIES

BOARD ON ENVIRONMENTAL STUDIES AND TOXICOLOGY

Proposal No. 10005942

(PR-ORD-22-01447/SOL 68HERC22R0228)

Technical Expertise Support on Environmental Protection Agency (EPA) Scientific Issues and
Topics 2022

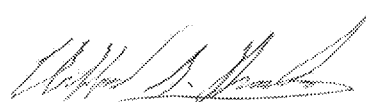
JULY 2022

**Russell
Walker**

Digitally signed by
Russell Walker
Date: 2022.07.20
11:40:20 -04'00'

for

James R. Burke
Director
Office of Contracts and Grants
National Academy of Sciences
Telephone: (202) 334-2428
E-mail: jburke@nas.edu



Clifford S. Duke
Board Director
Board on Environmental Studies and Toxicology
Division on Earth and Life Studies
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E-mail: cduke@nas.edu

This proposal is submitted by the NATIONAL ACADEMY OF SCIENCES (NAS), which assumes full technical and legal responsibility under its Act of Incorporation for the work to be carried out under any resultant agreement. The NAS is a private Federally chartered corporation exempt from federal income tax under Internal Revenue Service Code section 501(c)(3). The NAS Taxpayer Identification Number is 53-0196932. DUNS Number is 04-196-4057. **Awards resulting from this proposal should be issued to NATIONAL ACADEMY OF SCIENCES and payment directed to:**

National Academy of Sciences
Accounting Office
ATTN: Cash Management Section
500 Fifth Street, NW
Washington, DC 20001
Telephone: 202-334-3351 or 202-334-1476

(rev. 7/7/15)

THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE

DIVISION ON EARTH AND LIFE STUDIES

BOARD ON ENVIRONMENTAL STUDIES AND TOXICOLOGY

PROPOSAL NO: 10005942

TECHNICAL EXPERTISE SUPPORT ON ENVIRONMENTAL PROTECTION AGENCY
SCIENTIFIC ISSUES AND TOPICS 2022

SUMMARY:

The Board on Environmental Studies and Toxicology (BEST) proposes to assist the U.S. Environmental Protection Agency (EPA) with its evaluations of human health assessments by providing technical expertise for an EPA-hosted workshop.

Funding is requested to support the work conducted from September 1, 2022 through August 31, 2023. The estimated cost for the task specified in Solicitation No. PR-ORD-22-01447 is provided.

BACKGROUND:

The Center for Public Health and Environmental Assessment within EPA's Office of Research and Development develops human health and environmental assessments that support decision-making across the agency. The evaluations include Integrated Risk Information System (IRIS) assessments that identify and characterize the human health hazards (cancer and noncancer outcomes) of chemicals found in the environment.

Over the last decade, EPA has increased the transparency and rigor of its IRIS assessments in response to recommendations provided in several NASEM reports (NRC (2011) *Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde*; NRC (2014) *Review of EPA's Integrated Risk Information System (IRIS) Program*; and NASEM (2018) *Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation*). For example, EPA has formalized its IRIS assessment process for scoping and problem formulation by developing chemical-specific assessment plans and has implemented systematic-review approaches to evaluate the scientific literature.

EPA convenes public science meetings or workshops to encourage the scientific community and the general public to participate in discussions of IRIS draft assessment materials. The discussions are intended to address key science topics, such as systematic review, new assessment methods, hazard identification, and dose-response analysis. EPA considers the scientific information and perspectives obtained from the workshops as the IRIS assessment progresses.

One critical aspect for the success of EPA's science meetings or workshops is including participation by appropriate subject matter experts (SMEs) who provide input on various topics. NASEM is well suited to assist EPA in identifying SMEs, given its familiarity with EPA

assessments and its past assistance to the agency. Previously, NASEM staff has identified SMEs who participated in EPA-led workshops on various specific chemicals (e.g., naphthalene, phthalates, PCBs, and vanadium).

STATEMENT OF TASK:

The National Academies of Sciences, Engineering, and Medicine will assist the U.S. Environmental Protection Agency (EPA) by identifying experts for an EPA-led workshop to obtain information and views on scientific questions pertaining to the assessment of human health effects from exposure to cobalt. NASEM staff will gather nominations of potential participants and assess the relevance of their expertise, perspectives on the workshop questions, and possible conflicts of interest. After consultation with EPA personnel, NASEM staff will select up to four experts who will participate on their own behalf in the EPA-led workshop. NASEM will not host the workshop or produce any reports on the proceedings.

WORK PLAN:

NASEM will identify and recruit subject matter experts to provide input at one EPA-led workshop, which will be held to address key science issues pertinent to the development of a hazard assessment for cobalt. NASEM-identified experts will be selected to ensure diversity of scientific perspective and the absence of conflicts of interest or lack of impartiality. Identified experts will substantially contribute to achieving a balanced consideration to address scientific and technical issues discussed at the EPA-led workshop.

The National Academies are committed to enhancing diversity and inclusion in order to strengthen the quality of our work. Diverse perspectives contribute to finding innovative approaches and solutions to challenging issues. We encourage the nomination of volunteers who reflect the populations we serve and also welcome in particular nominations of candidates from underrepresented racial and ethnic groups, women, and early- and mid-career professionals.

EPA anticipates establishing a workshop date immediately upon award of this task order. Approximately 90 days prior to the date of the EPA-led workshop, agency personnel will inform NASEM staff of the workshop scope and the scientific issues to be addressed. An initial pre-meeting of EPA and NASEM personnel will be held within seven days after notification by EPA about the workshop scope and issues.

At the pre-meeting, EPA and NASEM personnel will review assessments and scientific/technical issues to be discussed at the EPA-led workshop. EPA will initiate a request for recruitment of experts through the generation of a one-page background document outlining the scope of the external EPA-led workshop and summarizing scientific issues that could include, but are not limited to, systematic review, new assessment methods, hazard identification, dose-response, and other relevant scientific issues to be discussed at the EPA-led workshop. NASEM will prepare a project milestone chart outlining the timeline for recruitment of experts and check-ins.

NASEM staff will identify a preliminary group of candidates who are recognized experts in relevant fields, representative of a range of broadly recognized views on the issues identified by

EPA, and available to present and discuss their individual views at the workshop. NASEM staff will screen candidates for potential conflicts of interest (COI) and sources of bias (lack of impartiality) according to whether the candidates have financial relationships with persons or organizations with an interest in a toxicological review of cobalt and whether the candidates have strong opinions concerning cobalt toxicity. In addition, project staff will ask whether an interested party would review the input the candidate would provide at the workshop. NASEM staff will provide the EPA TOCOR a proposed list of experts including biographical sketches and proposed area of expertise for each expert. The list of preliminary candidates will be completed no later than 30 days before the date of the external EPA workshop.

NASEM staff will convene a meeting between the EPA and NASEM personnel to review the preliminary list of experts. At the meeting, NASEM staff will consult with EPA personnel about the preliminary group of candidates concerning coverage of the science issues to be discussed at the workshop. Staff's evaluations of the candidates will be discussed with EPA but will not be communicated in writing. The evaluations will include consideration of any COI issues or lack of impartiality. EPA will provide comments on the proposed list regarding qualifications and COI/impartiality.

After receiving input from EPA, NASEM will determine who will participate in the EPA-led workshop. NASEM will deliver a final list of up to four participants no later than 2 weeks before the date of the EPA-led workshop.

NASEM staff will assist the experts to ensure participation in the EPA-led workshop. NASEM staff will provide workshop logistics information (e.g., webinar and teleconference information provided by EPA) to the selected experts. The workshop will be conducted virtually via the Internet.

Prior to the workshop, NASEM staff will convene an administrative meeting between EPA personnel and the NASEM-identified experts to discuss workshop logistics and to answer any questions about the workshop format.

At the EPA-led workshop, the experts selected by NASEM will comment on their own behalf. NASEM staff will compile any written input (e.g., optional individual PowerPoint slides) prepared by each expert on topics discussed at the EPA-led workshop. NASEM staff will submit the written input from the experts compiled in an appropriate format for EPA to post in the Regulations.gov chemical-specific docket after the EPA-led workshop.

DELIVERABLES:

1. A project milestone chart to be used to prepare for the EPA-led workshop will be provided to the EPA Contracting Officer (CO), Contract Level Contracting Officer Representative (CL COR), and TOCOR within seven days of when EPA confirms and notifies NASEM of the scientific/review topics anticipated to be discussed at the external EPA-led workshop. The project milestone chart will detail the significant activities in preparing for the workshop, as well as the expected progression of the other deliverables. EPA anticipates establishing a workshop date immediately upon award of this task order.

2. Primary products:

(a) Proposed and final lists of the names and biosketches of experts who would participate in the EPA-led workshop. The proposed list will be submitted no later than 30 days before the date of the EPA-led workshop. The final list of up to four expert participants will be delivered no later than 14 days before the date of the workshop.

(b) After reviewing the potential COI and impartiality issues for each expert, a verbal report of any issues will be offered to the EPA CO, CL COR, and ORD management. No written documents concerning NASEM staff's evaluation of the candidate participants will be submitted.

(c) If the experts involved in the workshop prepare any written comments or visual aids (such as optional PowerPoint slides), NASEM staff will compile the materials as non-consensus input and provide it to EPA in a format appropriate for posting in Regulations.gov chemical-specific docket after the EPA-led workshop.

3. Logistical support for participation by NASEM-identified experts in the EPA-led workshop, including convening an administrative meeting between EPA personnel and the experts prior to the EPA-led workshop to discuss workshop logistics and answer any questions about the workshop format. Because the workshop will be conducted virtually via the Internet, NASEM staff will not provide any transportation, lodging, or other logistical travel support to the experts.

FEDERAL ADVISORY COMMITTEE ACT (FACA):

Section 15 of the Federal Advisory Committee Act, 5 U.S.C. App., Section 15, does not apply to the activities described in this proposal. Section 15 of FACA restricts agency use of any advice or recommendations provided by the Academy that were developed by use of an Academy committee under an agreement with a Federal agency unless certain requirements are met. Those requirements do not apply to the work described in this proposal because the work does not involve either the use of an Academy committee or the provision of any advice or recommendations to a Federal agency.

PUBLIC INFORMATION ABOUT THE PROJECT:

In order to afford the public greater knowledge of Academy activities and an opportunity to provide comments on those activities, the Academy may post on its website (<http://www.nationalacademies.org>) the following information as appropriate under its procedures: (1) notices of meetings open to the public; (2) brief descriptions of projects; (3) committee appointments, if any (including biographies of committee members); (4) report information; and (5) any other pertinent information.

ESTIMATE OF COSTS:

Ex. 4 CBI

September 1, 2022 through August 31, 2023.

The period of performance is

A PERFORMANCE WORK STATEMENT

National Academies of Sciences, Engineering, and Medicine (NASEM)

Contract #68HERC19D0011

PR-ORD-22-01447/SOL 68HERC22R0228 Rev 1

Task Order #68HERC22XXXX

I. TITLE: Technical Expertise Support on Environmental Protection Agency (EPA) Scientific Issues and Topics 2022

II. Task Order Contracting Officer Representative(s):

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| Task Order Contracting Officer Representative (TOCOR) Name: Dahnish Shams Office: ORD/CPHEA/CPAD William Jefferson Clinton Building 1200 Pennsylvania Avenue, N.W. Mail Code: 8602R, Room No. 71205 Washington, DC 20460 Phone: (202) 564-2758 Email: shams.dahnish@epa.gov | Alternate Task Order Contracting Officer Representative (Alt. TOCOR) Name: Garland Waleko Office: ORD/CPHEA/CPAD Andrew W. Breidenbach Environmental Research Center 26 Martin Luther King Dr W Cincinnati, OH 45220 Phone: (513)-540-9426 Email: waleko.garland@epa.gov |
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III. PERIOD OF PERFORMANCE: Date of Award through 12 months following award.

IV. PURPOSE OF TASK ORDER

The purpose of this task order (TO) is to one (1) engage with the NASEM to provide the EPA with a mechanism to recruit NASEM identified subject-matter experts from the scientific community, to (2) address key science issues pertinent to the development of the hazard assessment for cobalt with independent scientific and technical input at one external EPA-led public meeting. This TO is a follow-on to TO 68HERC20F0025 (Task 1).

V. BACKGROUND

EPA's Center for Public Health and Environmental Assessment (CPHEA) is a leader in the science of human health and environmental risk assessments. CPHEA champions the development and use of health and environmental assessments by interacting with other agencies, the scientific community, industry, policy-makers, and the public. This TO would provide a mechanism to recruit scientific expertise and gain critical input from the experts identified by the NASEM. The NASEM is widely viewed as an impartial, knowledgeable, and respected organization, capable of ensuring audience acceptance of products with which it is associated. The NASEM is also able to provide EPA access to a full range of scientific and technical experts and to thoroughly screen such experts for conflicts of interest or lack of impartiality.

VI. SCOPE OF WORK

The NASEM shall provide the EPA with a mechanism to recruit NASEM identified subject-matter experts and when necessary, assist to provide a forum for discussion(s) on science topics pertinent to the development of the hazard assessment. The forum will be an external EPA-led public meeting/workshop that addresses key science topics including, but not limited to, systematic review, new assessment methods (NAM), hazard identification, dose-response, and other relevant scientific issues. NASEM shall not develop a consensus or non-consensus report associated with this task order.

VII. DESCRIPTION OF TASKS

Task 1. Recruitment of Technical Expertise to Support EPA Meeting or Workshop

NASEM shall identify and recruit subject matter experts (SME) to provide input at one (1) EPA-led meeting or workshop. NASEM-identified experts shall be selected to ensure diversity of scientific perspective and the absence of conflicts of interest or lack of impartiality. Identified experts shall substantially contribute to achieving a balanced consideration to address scientific and technical issues discussed at the EPA-led meeting or workshop. The following tasks shall be performed for the meeting or workshop.

Subtask 1.1 – Pre-Meeting: EPA will confirm and notify NASEM of the scientific/review topics anticipated to be discussed at the external EPA-led public meeting or workshop approximately 90 days prior to the external EPA-led meeting date. EPA anticipates establishing a meeting date immediately upon award of this task order. After notification, an initial EPA-NASEM pre-meeting shall occur within seven (7) days.

This pre-meeting is for EPA and NASEM to review assessments and scientific/technical issues to be discussed at the external EPA-led public meeting or workshop. NASEM shall prepare a project milestone chart outlining the timeline for recruitment and check-ins. EPA will initiate a request for recruitment of experts through the generation of a one-page background document outlining the scope of the external EPA-led public meeting/workshop and will also summarize scientific issues that could include, but are not limited to, systematic review, new assessment methods (NAM), hazard identification, dose-response, and other relevant scientific issues to be discussed at the external EPA-led public meeting/workshop and any pertinent work products(s).

Subtask 1.2 – Recruit Experts: Identify a proposed group of up to four (4) SMEs who are (a) recognized experts in the field(s) relevant to the request, (b) represent a range of broadly recognized views on the issues identified by EPA, (c) are available to present and discuss their individual views at the meeting or workshop, and (d) have been evaluated for conflict of interest or lack of impartiality. This should be completed no later than 30 days before the external EPA-led public meeting/workshop date.

Subtask 1.3 – Post-Recruitment Meeting: Convene a meeting between the EPA and NASEM to review the proposed list of SMEs. NASEM shall provide the EPA TOCOR a proposed list of SMEs

including a biographical sketch, proposed area of expertise for each SME, and if there are any issues regarding potential conflict of interest (COI) or impartiality.

EPA will provide comments on the proposed list regarding qualifications and COI/impartiality. NASEM shall determine who will participate in each meeting or workshop. NASEM shall then deliver a final list of participants no later than 2 weeks before the EPA-led meeting date.

Subtask 1.4 – Coordinating Expert Logistic Support for SME Participation: NASEM shall provide meeting logistics information (e.g., webinar and teleconference information provided by EPA) to the SMEs. This meeting will be conducted virtually via webinar. NASEM shall convene a meeting between the EPA and the NASEM-identified SMEs prior to the EPA-led meeting or workshop to discuss the meeting logistics and to answer any questions. NASEM shall assist SMEs to ensure participation in the EPA-led meeting or workshop.

Subtask 1.5 – Comment Compilation: NASEM shall compile non-consensus input (e.g., optional individual PowerPoint slides summarizing key remarks) from each SME as needed on topics discussed at the EPA-led meeting/workshop for delivery to EPA. NASEM shall ensure that the compiled SME input is in an appropriate format for EPA to post in the Regulations.gov chemical-specific docket after the EPA-led meeting.

VIII. Deliverables

The products of the NASEM tasks for activity are as follows:

Task 1 Deliverables

- a) EPA requests that a project milestone chart used to prepare for the EPA-led meeting be provided to the EPA Contracting Officer (CO), Contract Level Contracting Officer Representative (CL COR), and TOCOR at the EPA-NASEM pre-meeting that shall occur within seven (7) days of when EPA confirms and notifies NASEM of the scientific/review topics anticipated to be discussed at the external EPA-led public meeting or workshop (Subtask 1.1). This project milestone chart should detail the significant activities for the meeting, as well as expected progression of the deliverables.
- b) The primary products for the meeting are expected to be: (a) proposed and final lists of SMEs, including biographical sketches, who will participate in the EPA-led meeting or workshop (b) review of potential COI and partiality issues for each expert and report of any potential issue to the EPA CO, CL COR, and ORD management, and (c) provide compiled non-consensus comments from each expert to provide to EPA that will be posted in Regulations.gov.
- c) Provision of logistical support for SME participation in the EPA-led meeting or workshop, including convening a meeting between the EPA and the NASEM identified SMEs prior to the EPA-led meeting or workshop to discuss the meeting logistics and to answer any questions.

IX. ACCEPTANCE CRITERIA

The Contractor shall prepare high quality products and that are reproducible and transparent. Figures submitted shall be of high quality, similar to presentations developed for national scientific forums, and should be formatted as jpeg or TIFF files. Deliverables shall be edited for grammar, spelling, typographical errors, as well as logic flow, technical accuracy, completeness, and conformance with the specific task, charge, expertise, and deliverables of this Performance Work Statement. Deliverables should be completed in a timely manner. Written deliverables shall be provided in Microsoft Word 2010, Adobe Acrobat, or compatible format. Deliverables will be accepted upon review and approval by the TOCOR.

THE NATIONAL ACADEMY OF SCIENCES

DIVISION ON EARTH AND LIFE STUDIES

BOARD ON ENVIRONMENTAL STUDIES AND TOXICOLOGY

Proposal No. 10005942

Technical Expertise Support on Environmental Protection Agency (EPA) Scientific Issues and Topics 2022

EPA Cumulative Summary Estimate of Costs

9/1/22 to 08/31/23

Ex. 4 CBI

Amount Requested from EPA

Ex. 4 CBI

It is requested that the award will provide for payment
via Letter of Credit or electronic transfer.

Footnote: These major cost categories reflect the billing structure used by the National Academy of Sciences. Cost and rate data are attached as background information. Please be advised, however, that all costs are systematically collected in our accounting system and are available for audit through arrangements with the Defense Contract Audit Agency and our cognizant Administrative Contracting Officer at the Office of Naval Research.

THE NATIONAL ACADEMY OF SCIENCES

DIVISION ON EARTH AND LIFE STUDIES

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THE NATIONAL ACADEMY OF SCIENCES

DIVISION ON EARTH AND LIFE STUDIES

BOARD ON ENVIRONMENTAL STUDIES AND TOXICOLOGY

Proposal No. 10005942

Technical Expertise Support on Environmental Protection Agency (EPA) Scientific Issues and Topics 2022

Estimate of Costs

9/1/22 to 8/31/23

12 months

Ex. 4 CBI

Ex. 4 CBI

1.

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Ex. 4 CBI

Ex. 4 CBI